# In the United States Court of Federal Claims

No. 02-0411V
Filed: July 17, 2008
**TO BE PUBLISHED**

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| JOHN DOE 21, | * | |
| | * | Causation-In-Fact; |
| Petitioner, | * | National Vaccine Injury Act, |
| | * | 42 U.S.C. § 300 aa-1 *et seq*.; |
| v. | * | Remand; |
| | * | Treating Physician. |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| | * | |
| Respondent. | * | |

**John H. McHugh**, New York, New York, Counsel for Petitioner.

**Michael P. Milmoe**, United States Department of Justice, Washington, D.C., Counsel for Respondent.

**MEMORANDUM OPINION AND FINAL ORDER REGARDING THE JANUARY 16, 2009 DECISION ON REMAND DENYING ENTITLEMENT.**

**BRADEN, *Judge*.**

As previously discussed, this proceeding was far from what the court expects from the Office of the Special Masters. *See John Doe 21* v. *Sec'y of HHS*, 84 Fed. Cl. 19, 20 (2008) ("*John Doe 21*"). Taking six years before a case initially is brought to the court for review is inexcusable. *Id*. Likewise, as previously noted, in the court's judgment, Petitioner's counsel did not approach this case with proper attention to precedent or with the amount of diligence that the court expects. *Id*. at 49. The court is aware that non-Table vaccine cases are difficult to prove for a variety of reasons. Most are handled on a contingency basis, limiting the available resources that can be devoted to any one individual case. The perspective of medical professionals who have treated a petitioner often differ. Many children do not see the same pediatrician during their first critical months, so that subtle but important symptoms may be missed. For this reason, the opinion of a physician who has had a long personal relationship with a patient is afforded more deference than an expert retained for litigation. In addition, highly specialized physicians who have not examined, much less treated,

a patient understandably are reluctant to second-guess the opinion of a well qualified peer, particularly where medical records are many years old and were not made with the intent of satisfying the requisite specificity required to establish causation-in-fact under the Nation Childhood Vaccine Act of 1986, 42 U.S.C. § 300 aa-1 *et seq*. (2006) (the "Vaccine Act").

The January 16, 2009 Decision on Remand Denying Entitlement reflects a substantial amount of work conducted in an expedited time frame by the third Special Master assigned to this case. *See John Doe 21* v. *Sec'y of HHS* at *1 (Fed. Cl. Spec. Mstr. Jan. 16, 2009) ("*Remand Decision*"). Despite this effort, the court has determined that the Remand Decision erroneously concluded that:

> A preponderance of the evidence establishes that Child Doe started to show some signs of developmental delay in January 2000, which was diagnosed in March 2000. [Petitioner] has failed to establish that Child Doe's developmental delay was caused by the vaccination, which he received months earlier. Alternatively, Mr. Doe failed to establish that any adverse reaction to the July 20, 1999 DTaP vaccine lasted more than six months. Consequently, he is not entitled to compensation.

*See Remand Decision* at *1.

To facilitate review of this Memorandum Opinion and Final Order, the court has provided the following outline:

**I. RELEVANT FACTS.**

**II. PROCEDURAL HISTORY.**

**A. The Initial Special Master Proceeding.**

**B. The Initial United States Court Of Federal Claims Proceeding.**

**C. The Remand Proceeding Before Special Master III.**

**D. Current Proceeding Before The United States Court Of Federal Claims.**

**III. DISCUSSION.**

**A. Jurisdiction And Standard Of Review.**

**B. Causation In Vaccine Act Cases.**

**C. Petitioner's February 17, 2009 Motion For Review.**

**1. Petitioner's Argument.**

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## I. RELEVANT FACTS.[1]

[1] The relevant facts herein initially were set forth in *John Doe 21*, 84 Fed. Cl. at 20-34 citing: October 2, 2002 Defendant's ("Government" or "Gov't") Notice of Filing with 9/1/02 Declaration of Mr. Doe; 9/19/02 Letter from Dr. Victor Turow, M.D., F.A.A.P., Pediatrician; July 2002 Declaration of Angela Rose Dazzo; Undated Certification of Loretta Costello; Exhibit A – 5/11/99 Birth Certificate; Exhibit B – Records of North Shore University Hospital; Exhibit C – Records of Mark N. Goldstein, M.D., F.A.C.S., F.A.A.P., Pediatric Ophthalmology; Exhibit D – Records of Dr. Mark J. Kupersmith, M.D., New York Eye and Ear Infirmary, Institute for Neurology and Neurosurgery Beth Israel Medical Center; Exhibit E – Records of Dr. Michael L. Slavin, M.D., Residency Program Director, Chief Neuro-Ophthalmology, Medical Retinal Diseases, Long Island Jewish Medical Center; Exhibit F – Records of Dr. Robert J. Gould, M.D., Metropolitan Pediatric Neurology, P.C.; Exhibit G – Records of Dr. R.R. Branccio, M.D., Bayridge Dermatological Assoc.; Exhibit H – Records of Dr. Robert Hayman, M.D., F.A.A.P., Pediatric Dermatology; Exhibit I – Letter from Dr. Neil S. Sadick, M.D. Sadick Aesthetic Surgery & Dermatology; Exhibit J – Records of Dr. R.R. Branccio, M.D., Bayridge Dermatological Assoc.; Exhibit K – Records of Nassau County System (New York) – Children's Health Network Early Intervention Program; Exhibit L – Records of North Shore - Long Island Jewish Health and Manhasset Schools; Exhibit M – Records of Dr. Mark J. Kupersmith, M.D., New York Eye and Ear Infirmary, Institute for Neurology and Neurosurgery Beth Israel Medical Center; Exhibit N – Records of Dr. Neil S. Sadick, M.D., Sadick Aesthetic Surgery & Dermatology; October 10, 2002 Petitioner Notice Of Filing (September 20, 2000 letter from Dr. Steven Pavlakis, M.D.); July 29, 2005 Petitioner Exhibits A (**"**May 16, 2005 operative note of Dr. Neil A. Feldstein, New York Presbyterian Hospital-Columbia") and B ("April 28, 2005 Consultation Report, Neurosurgical Associates, New York, Presbyterian Medical Center, New York"); September 15, 2005 Exhibit 302-93 (records from the Columbus Presbyterian Medical Center); October 27, 2005 hearing limited to fact testimony (10/27/05 TR 4-147); October 28, 2005, hearing limited to medical testimony (10/28/05 TR 203-380); October 31, 2005, Petitioner filing including prescriptive pad note of Dr. Eviatar and two photographs of Petitioner; November 4, 2005, Government Exhibits C and D; December 29, 2005 Petitioner Filing with Ex. 1 – 12/29/05 Nassau

On May 11, 1999, Petitioner was born after a routine pregnancy. *See* 10/2/02 Gov't Ex. B at 2-25. At birth, Petitioner weighed six pounds, twelve ounces, and measured nineteen and one-half inches in length. *Id*. at 3; *see also* 7/11/06 Pet. Ex. A at 1. On May 24, 1999, Petitioner had a "healthy" two week examination and was beginning to hold his head and was responding to sound and light. *See* 10/2/02 Gov't Ex. B at 30. On June 10, 1999, Petitioner had a one month examination, and he was found to be normal, except for constipation, and otherwise was "alert comfortable." 7/11/06 Pet. Ex. A at 5.

On July 20, 1999, Petitioner's constipation continued, but Dr. Earhardt, from the Department of Pediatrics of the North Shore University Hospital (New York), noted that Petitioner "roll[ed] side to side, lifts head very well, coos vocalizes, focuses on face, turns to voice, smiles." 10/2/02 Gov't Ex. B at 34. Petitioner's assessment was "healthy." *Id.* On that date, Petitioner received diphtheria-tetanus-pertussis ("DTaP"), inactivated poliovirus ("IPV"), and COMVAX™,[2] Hib, and Hepatitis B vaccinations. *Id*. at 32.

On the evening of July 20, 1999 at 9:47 p.m., Petitioner was admitted to the North Shore University Hospital Emergency Department with a fever of 101°F. *Id*. at 34B. The primary complaint "per mother" was "crossed eyes, moaning, acting unusual." *Id*. at 34A. The triage nurse

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Radiologic Group, P.C.; Ex. 2 – 6/23/00 Nassau Radiologic Group, P.C.; Ex. 3 – 5/10/05 Long Island Jewish Medical Center, Department of Radiology; Ex. 4 – 6/7/05 Neurological Associates at New York Presbyterian Medical Center in New York; Ex. 5 – 11/21/05 Dr. Steven Pavlakis letter; Ex. 6 – 11/21/05 Dr. Eugene B. Spitz, M.D., Diagnostic & Treatment Center for Central Nervous System Disorders, Inc.; July 11, 2006, Petitioner's Exhibit A; Exhibit B (records of Dr. Palvakis); Exhibit C (note from Dr. Marvin Boris); July 24, 2006, Petitioner's Exhibit A (Report of May 3, 2002 MRA) and Exhibit B (Report of May 2, 2002 MRI); November 13, 2006, Petitioner's Exhibit A (Expert Report of Dr. Steven Pavlakis) and Exhibit B (Expert Report of John D. Shane); January 30, 2007, Petitioner's Filing Of Medical Records (records from Beth Israel Medical Center); February 15, 2007, Government Supplemental Expert Report of Dr. Wiznitzer.

[2] "COMVAX™" is a "trademark for a combination preparation of *Haemophilus* b conjugate vaccine and hepatitis B vaccine (recombinant)." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 403 (27th ed. 1988) ("DORLAND'S").

noted that Petitioner received a DTaP vaccine on that same date and developed a fever. *Id*. at 34B.[3] The resident physician examination noted a rectal temperature of 101.3◦F, an "enlarged thyroid," and "adenopathy."[4] *Id*. at 34B. The attending physician noted: "fever & a 10 minute episode of eye crossing, without tonic/clonic activity,[5] drooling[.]" *Id*. Subsequent tests, including blood and urine samples were negative. *Id.* at 36-44, 46-47. A neurological examination showed no "focal deficits" and a regular flat fontanelle.[6] *Id.* at 34C. Petitioner was diagnosed with a fever, advised to take "Tylenol," and Ms. Doe was instructed to "follow up with" Petitioner's pediatrician "in the morning." *Id.* at 34D. Petitioner was released from the Emergency Room around 11:00 p.m. in "satisfactory" condition. *Id.*

Petitioner's fever, however, did not abate. *Id.* at 45. On July 21, 1999, Petitioner's mother reported that her son still had a temperature of 101◦F. *See* 7/11/06 Pet. Ex. A at 8.

On July 28, 1999, Petitioner's medical records show that both eyes had "no tears" and were "crusty," but Petitioner was "alert; awake . . . [and his] neck [was] supple." 10/2/02 Gov't Ex. B at 48.

During an August 19, 1999 examination when Petitioner was 3 ½ months, he experienced another fever episode of 101◦F, was "cranky," but "alert" and "active," with a "neck supple." *Id*.

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[3] In 1994, the Institute of Medicine ("IOM") also reported that:

> DPT [has] been known to cause fever, they have been associated with the occurrence of acute febrile seizures [*i.e.*, "those associated with high fever, occurring in infants and children." DORLAND'S at 415]. Febrile seizures alone do not lead to a residual seizure disorder . . . there are no data directly nearing on the biologic plausibility of a relationship between diphtheria or tetanus toxins and residual seizure disorder.

1994 IOM REPORT at 79.

[4] "Adenopathy" is the "swelling or morbid enlargement of the lymph nodes." STEDMAN'S MEDICAL DICTIONARY 755 (28th ed. 2006) ("STEDMAN'S").

[5] A "generalized tonic-clonic seizure" is a "seizure of grand mal epilepsy, consisting of loss of consciousness and generalized tonic convulsions followed by clonic convulsions." DORLAND'S at 1676. "Grand mal epilepsy" is a "symptomatic form of epilepsy often preceded by an aura; characterized by loss of consciousness with generalized tonic-clonic seizures." *Id*. at 628.

[6] A "fontanelle" is "[o]ne of several membranous intervals between the angles and margins of the cranial bones in the infant." STEDMAN'S at 755.

Other tests were unremarkable. *Id*. Because Petitioner's older sister was also ill,[7] the physician assumed the cause of these symptoms was a "viral syndrome." *See* 7/11/06 Pet. Ex. A at 8.

On September 14, 1999, Dr. Steve Barrone, another member of the Department of Pediatrics of the North Shore University Hospital, determined that Petitioner was "well," except for a "discharge" from the left eye that could possibly be a duct "obstruction," but noted that Petitioner "sits[8], holds [his] head," "babbles," and otherwise was "social." 10/2/02 Gov't Ex. B at 51. On this occasion, DT, IVP, and COMVAX™ vaccinations were administered, but the pertussis[9] portion was not administered, because of the July 20, 1999 "hypotonic-[illegible] episode."[10] *Id*. at 52; *see also* 7/11/06 Ex. A. at 1.

From September 23 to October 7, 1999, Petitioner was examined by several physicians from the Department of Pediatrics of the North Shore University Hospital at least five times for otitis[11] and thrush.[12] *See* 10/2/99 Gov't Ex. B at 53-55. On September 23, 1999, Petitioner's parents reported that he would not take a bottle, was up all night crying with coughing and congestion, but had no fever. *Id*. at 53. The diagnosis was "nasal thrush" and a prescription for Nystatin™[13] was issued for one week. *Id*. On September 24, 1999, Petitioner's physician noted that Petitioner was

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[7] Petitioner's sister was born on May 29, 1995. *See* 10/2/02 Gov't Ex. B at 32.

[8] At the December 2, 2008 remand hearing, Dr. Turow found this entry vague, stating "I don't know what that means." *See* 12/2/08 TR at 1085. Dr. Turow was uncertain if the notation referred to sitting with support or without support. *Id.*

[9] Pertussis vaccine is "a suspension of killed *Bordetalla pertussis* organisms (whole cell vaccine) or a fraction thereof (acellular) either fluid (pertussis vaccine [USP] or absorbed on aluminum hydroxide or aluminum phosphate and resuspended (pertussis vaccine absorbed [USP]); used for routine immunization against pertussis (whooping cough). It is generally used in a mixture of diphtheria and tetanus toxoids. (DTP or DTaP)." DORLAND'S at 1999.

[10] "Hypotonia" is "a condition of diminished tone of the skeletal muscles; diminished resistance of muscles to passive stretching." DORLAND'S at 900.

[11] "Otitis" is an "inflammation of the ear." STEDMAN'S at 1394.

[12] "Thrush" is an "[i]nfection of the oral tissues with *Candida albicans* . . . common in normal infants who have been treated with antibiotics." STEDMAN'S at 1986.

[13] "Nystatin™" is a "polyene antifungal agent . . . used in the treatment of . . . candidal infections[.]" DORLAND'S at 1296.

"more cranky - fever today." *Id*. Augmentin™,[14] an antibiotic, was prescribed, and Nystatin™ was suspended. *Id*.

On October 4, 1999, Dr. Victor Turow, M.D., F.A.A.P. from the Department of Pediatrics of the North Shore University Hospital, noted a "l[eft] strabismus"[15] or "psuedostrabismus,"[16] and recommended an ophthalmologic consultation. *Id.* at 54. On October 5, 1999, Petitioner was reported to be "kvethcy all night," exhibiting "blurred eyes," and "reddened ears." *Id*.

On November 8, 1999, Petitioner was diagnosed by Dr. Turow with an "u[pper] r[espiratory] i[llness]" and "nasal congestion." *Id.* at 56. Although Dr. Turow observed that Petitioner had not rolled over and could not "sit up [without] support," Petitioner was diagnosed as a "well infant," because he exhibited "good head control" and was able to grab "onto objects well." *Id.* On that date, a DT vaccine was administered, but without pertussis. *Id*. at 32, 57; *see also* 7/11/06 Ex. A at 1.[17] Petitioner also was referred to Dr. Strove for a left eye "deviation medially." 10/2/02 Gov't Ex. B at 57.

On November 10, 1999, Dr. Steven E. Rubin, MD, a pediatric ophthalmologist, found Petitioner to be a "healthy 6 month old baby with a suspected esotropia"[18] and noted "crusting from the left eye." *Id.* at 59. Dr. Rubin, however, found no evidence of strabismus and suggested that the esotropia "would probably spontaneously resolve over the next several months." *Id.*

On November 15, 1999, Petitioner again was examined by a physician in the Department of Pediatrics of the North Shore University Hospital for eye crusting, nasal discharge, chest congestion, and fever of 101°F, but was diagnosed with a viral syndrome and conjunctivitis. *Id*. at 58. Nasal suctioning, a humidifier, and eye drops were prescribed. *Id*. On November 22, 1999, Petitioner was

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[14] "Augmentin™" is a "trademark for combination preparations of amoxicillin and clavulanate potassium." DORLAND'S at 179.

[15] "Strabismus" is "[a] manifest lack of parallelism of the visual axes of the eyes." STEDMAN'S at 1841.

[16] "Psuedostrabismus" is "[t]he appearance of strabismus caused by epicanthus, abnormality in interorbital distance, or corneal light reflex not corresponding to the center of the pupil." STEDMAN'S at 1593.

[17] Petitioner's November 8, 1999 medical records indicated that pertussis should not be administered, because of Petitioner's adverse reaction on July 20, 1999. *See* 10/2/02 Gov't Ex. B at 57.

[18] "Estropia" is a form of strabismus involving "manifest deviation of the visual axis of an eye toward that of the other eye." DORLAND'S at 583.

examined for nasal congestion, a continuing cough, and vomiting twice on November 21, 1999. *Id*. Petitioner was diagnosed with otitis media and prescribed Augmentin™. *Id*.

On December 4, 1999, Petitioner cried all night with aches and fever. *Id*. at 61. Petitioner's records indicated teething, but Petitioner also was experiencing thrush. *Id*. Significantly, however, plagiocephaly[19] was observed. *Id.* at 61. An appointment was recommended to examine Petitioner's head circumference and "development." *Id*.

On December 10, 1999, Petitioner was "cranky and up all night; the examination confirmed the right ear had a yellow bulging effusion." *Id*. Cefzil™,[20] a different antibiotic, was prescribed. *Id*. On December 22, 1999, Petitioner's ear was checked by Dr. Turow and still found to be "mucusy," despite having taken Cefzil™. *Id*. at 62. In addition, Petitioner had "mucusy eyes" with redness and haziness, but no pus. *Id*. On December 24, 1999, Dr. Turow ordered a Ceftriaxone[21] injection #2 (400 mg) and issued a prescription for Gantrisin™.[22] *Id*. On December 27, 1999, Petitioner was examined and received a third shot of Ceftriaxone. *Id*. at 63.

On January 3, 2000, Dr. Turow noted that: "Petitioner was crying all day [January 2, 2000]; experienced a fever of 101-102°F; was sneezing and coughing; with congestion evident." *Id*. On January 8, 2000, Petitioner again was crying non-stop, with a low-grade temperature, despite being on Gantrisin™. *Id*. The antibiotic was changed to a combination of Amoxicillin[23] and Augmentin™. *Id*. On January 14, 2000, Petitioner was re-checked to ascertain his reaction to the new antibiotics. *Id*. at 64. On January 19, 2000, Petitioner's physician observed that Petitioner's infection was improved, and the physician re-instated Gantrisin™. *Id*.

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[19] "Plagiocephaly" is an "unsymmetrical and twisted condition of the head, resulting from irregular closure of the cranial sutures." DORLAND'S at 1301.

[20] "Cefzil™" is a "trademark for cefprozil" a "synthetic broad-spectrum, second-generation cephalosporin effective against a wide range of gram-negative and gram-positive organisms, used in the treatment of otitis media and infections of the respiratory and oropharyngeal tracts, skin, and soft tissues; administered orally." DORLAND'S at 315; *see also Id.* at 314.

[21] "Ceftriaxone" is a "semi-synthetic, broad-spectrum, third generational cephalosporin antibiotic, which acts by inhibiting enzymes responsible for cell-wall synthesis; effective against gram-positive and gram-negative bacteria; administered intravenously and intramuscularly." DORLAND'S at 314-15.

[22] "Gantrisin™" is a "trademark for preparations of sulfisoxazole." DORLAND'S at 755. "Sulfisoxazole" is a "short-acting sulfonamide used as a antibacterial in the treatment of a wide variety of infections, particularly in the urinary tract[.]" *Id*. at 1791.

[23] "Amoxicillin" is a "semisynthetic derivative of ampicillin . . . used . . . in the treatment of infections[.]" DORLAND'S at 64.

On January 31, 2000, Petitioner received a Hepatitis B immunization. *Id*. at 65. On January 31, 2000, Petitioner's physician observed that Petitioner could: sit without support; use a "pincer grasp;" speak; wave; and play "peek-a-boo." *Id*. Petitioner was diagnosed as "well," despite the fact he could not pull "to stand" or "cruise." *Id.*

On February 7, 2000, Petitioner was examined for a possible ear infection, being irritable all day and night, mild nasal congestion, and decreased appetite. *Id*. at 66. On February 17, 2000, Petitioner experienced vomiting, intermediate diarrhea, a "wet cough," and fever. *Id*. at 67. By February 19, 2000, Petitioner still was not keeping food down, was "very cranky," had a bad cough, and was very congested. *Id*.

On March 8, 2000, when Petitioner's ear was re-checked, Dr. Turow also noted potential increased "tone" [24] in Petitioner's extremities and noted concern about Petitioner's "developmental progression." *Id*. at 68. On March 16, 2000, Petitioner was examined for chronic coughing, congestion, and crying and was referred to an Ear Nose and Throat ("ENT") specialist. *Id*. at 69.

On March 17, 2000, Petitioner also had a "head ultrasound" for "enlarged head size." *Id*. at 70. The ultrasound revealed "[p]rominent extra-axial spaces" consistent with "benign external hydrocephalus."[25] *Id*.

On March 27, 2000, Petitioner was examined for crying, cough, running nose, and recurrent otitis. *Id*. at 69. On March 29, 2000, Petitioner was examined by an ophthalmologist and ENT, and for the first time "vertical nystagmus"[26] was noted. *Id.* Petitioner also was examined by Dr. James Fagin, M.D., from the Nassau County Early Developmental Intervention Program, who concluded Petitioner had "developmental delay." 10/2/02 Gov't Ex. L at 240.

On March 29, 2000, Petitioner was examined by the Louise Oberkotter Early Childhood Center, where he was evaluated in "eight areas of development: Gross Motor; Fine Motor; Relationship to Inanimate Objects; Language/Communications; Self-Help; Relationship to Persons; Emotions and Feeling States; and Coping Behavior." *Id.* at 219-23. Petitioner's scores in the categories of Gross Motor, Fine Motor, Language/Communication, and Emotions and Feeling States were "Of Concern." *Id.* at 223. "Physical Therapy services to address delay in gross motor skill

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[24] "Tone" is the normal degree of vigor and tension, in muscle, the resistance to passive elongation or stretch." DORLAND'S at 1919.

[25] "Hydrocephalus" is a "condition marked by an excessive accumulation of cerebrospinal fluid resulting in dilation of the cerebral ventricles and raised intracranial pressure; it may also result in enlargement of the cranium and atrophy of the brain." STEDMAN'S at 910.

[26] "Nystagmus" is the "[i]nvoluntary rhythmic oscillation of the eyeballs, either pendular or with a slow and fast component." STEDMAN'S at 1350.

acquisition" was recommended. *Id*. In addition, monitoring Petitioner's "fine motor function" and "Speech and Language development" was recommended. *Id.*

On March 30, 2000, Petitioner's physician noted that Petitioner's mother observed Petitioner's "vertical nystagmus, seems to be getting worse." 10/2/02 Gov't Ex. B at 71. Subsequently, Dr. Robert J. Gould, M.D., a pediatric neurologist, ran a series of tests, but was unable to observe any "vertical nystagmus." *Id.*; *see also* 10/2/02 Gov't Ex. F at 179. Dr. Rubin's re-examination on April 5, 2000 also did not evidence nystagmus. *See* 10/2/02 Gov't Ex. B at 72.

On April 24, 2000, Dr. Mark N. Goldstein, M.D., a pediatric otolaryngologist ("Dr. Goldstein"), scheduled Petitioner for a bilateral myringotomy[27] and placement of tubes due to "effusions"[28] in Petitioner's ears. *Id*. at 75. On April 24, 2000, Dr. Goldstein and Dr. Rubin's recommendations were reviewed by Dr. Turow. *Id*. Although Dr. Turow agreed that a myringotomy procedure was indicated, he also recommended a neurological evaluation. *Id*. Subsequently, Petitioner entered an early intervention physical therapy program to address his developmental delay. *See* 10/2/02 Gov't Ex. L at 236.

On April 28, 2000, Dr. Steven G. Pavlakis, M.D., Director, Division of Pediatric Neurology and Developmental Medicine and Professor of Pediatrics, Mount Sinai School of Medicine ("Dr. Pavlakis"), examined Petitioner for occasional "up and down eye fluttering" and "upper eyelid fluttering," without "alteration of consciousness." 10/2/02 Gov't Ex. B at 78-79. Dr. Pavlakis noted that Petitioner regularly was alert, active, and interactive for someone his age, but also was delayed "in regard to motor milestones." *Id.* Dr. Pavlakis concluded that Petitioner had mild hypotonia,[29] "trembling in both arms," and "mild tremors." *Id.* Dr. Pavlakis was not overly concerned with Petitioner's eye and eyelid fluttering and, after reviewing a video of Petitioner's "atypical eye movements," did not believe they were "seizures." *Id.* at 79.[30] Dr. Pavlakis, however, did consider these episodes "a little atypical." *Id*. Petitioner, however, was referred to Dr. Mark J. Kupersmith, a neuro-ophthalmologist ("Dr. Kupersmith"), because Petitioner in fact may have had "epilepsy." *Id.* at 78-79.

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[27] A "myringotomy" is "the creation of a hole in the tympanic membrane[.]" DORLAND's at 1217.

[28] An "effusion" is "[t]he escape of fluid from the blood vessels or lymphatics into the tissues or a cavity." STEDMAN'S at 616.

[29] "Hypotonia" is "[a] condition in which there is a diminution or loss of muscular tonicity." STEDMAN'S at 939.

[30] *See* Pl. 10/10/02 letter from Dr. Pavlakis explaining that on April 28, 2000 Petitioner did experience "an event consistent with seizure." It appears that the symptom was not "eye fluttering," but a "trembling" and "mild tremor." *See* 10/2/02 Gov't Ex. B at 78-79.

On May 8, 2000, Dr. Goldstein conducted pre-admission testing, a medical history, and an examination in preparation for a double myringotomy procedure, because of fluid in Petitioner's middle ear. *See* 10/2/02 Gov't Ex. C at 144-46. Dr. Goldstein was aware that Petitioner's past medical history noted "? seizure after DPT. Delayed fine motor skills, now in early intervention." *Id*. at 144.

On May 22, 2000, Petitioner again had a fever with transient vomiting/diarrhea. *See* 10/2/02 Gov't Ex. B at 82. Dr. Turow rescheduled Petitioner's vaccinations for one to two weeks later. *Id*. Petitioner was diagnosed as having "developmental delay." *Id*. Petitioner also had an Electroencephalography Study ("EEG") as requested by Dr. Pavlakis. *Id*.

On May 24, 2000, Petitioner had a 103◦F fever, vomiting, and diarrhea. *Id*. at 83. He was alert, but "clingy and lethargic." *Id*. On May 31, 2000, Petitioner continued to experience crankiness, but his ears seemed to be better after having tubes inserted. *Id*.

On June 7, 2000, Dr. Kupersmith, M.D., Chief of the Division of Neuro-Ophthamology at the Institute for Neurology, Beth Israel Medical Center in New York, examined Petitioner for the "abnormal or involuntary" movement of his eyes and eyelids. *See* 10/2/02 Gov't Ex. F at 179. Dr. Kupersmith did not observe any irregular activity, but observed a video tape provided by Ms. Doe that showed Petitioner during an episode. *See* 10/2/02 Gov't Ex. D at 168. Nevertheless, Dr. Kupersmith did not believe that Petitioner's irregular eye movements were related to a seizure, but concluded that the activity was "upper lid retraction," rather than "any significant eye muscle involvement or nystagmus." *Id.* Nevertheless, Dr. Kupersmith was concerned about Petitioner's "head size," and recommended a Magnetic Resonance Imaging ("MRI") to determine whether Petitioner had "hydrocephalus, causing posterior third ventricle dilation." *Id.*

On June 12, 2000, when Petitioner was thirteen months old, Dr. Turow noted that Petitioner was sitting, recently crawling, still raking his hands, clapping and waving, and understood "no." 10/2/02 Gov't Ex. B at 84.

On June 13, 2000, Petitioner also had an EEG at North Shore Hospital that was reported to be "within the normal limits." *Id*. at 85. Petitioner had to be sedated, because he was experiencing "fluttering eye and hand shaking." *Id*. The responsible physician reported that Petitioner also may have exhibited signs of "hypnogogic hyper synchrony,"[31] but the photic stimulation was not abnormal and no clear epileptiform activity was seen. *Id*. On June 22, 2000, Dr. Joseph L. Zito ("Dr. Zito") performed a cranial MRI that also revealed "no evidence of mass effect" in the "ventricular system and subarachnoid spaces," and "no extraaxial mass or fluid collection." *Id.* at 98*; see also* 12/29/05 Pet. Ex. at 4 . Dr. Zito concluded that Petitioner's MRI was "normal." 10/2/02 Gov't Ex. B at 98*; see also* 12/29/05 Pet. Ex. at 4.

[31] This term is not defined either in DORLAND'S or STEDMAN'S. "Synchrony," however, is defined as "[t]he simultaneous appearance of two separate events." STEDMAN'S at 1887.

On June 26, 2000, Petitioner was examined for an eye infection. *See* 10/2/02 Gov't Ex. B at 84. On June 27, 2000, Petitioner had a follow-up examination regarding the bilateral myringotomy and tube insertion. *See* 10/2/02 Gov't Ex. C at 143. Petitioner again was reported as experiencing "some blinking of the eyes upon arising." *Id.*

On July 12, 2000, Petitioner received a measles-mumps-rubella ("MMR") immunization and a VARIVAX immunization. *See* 10/2/02 Gov't Ex. B at 102. On July 26, 2000, Petitioner was examined for diarrhea and some spitting up. *Id.*

On August 11, 2000, Dr. Turow diagnosed Petitioner with an upper respiratory infection. *Id.* at 103. More importantly, Petitioner's "vertical nystagmus" was of sufficient concern that he was referred to a neurologist. *Id.*

On September 6, 2000, Petitioner was examined for crankiness and crying in his sleep, and the physician concluded that those symptoms were attributed to teething. *Id.*

On September 13, 2000, Petitioner was observed to have "developmental delay," but was "progressing." *Id.* at 99. The physician also noted "intermittent but daily vertical nystagmus." *Id.* On that date, a DT vaccination was administered, without pertussis, because of Petitioner's prior reaction. *Id.* at 32, 99. In addition, an IPV vaccine was administered. *Id.*

On September 26, 2000, Dr. Pavlakis examined Petitioner and recommended a 24-hour EEG and another evaluation by Dr. Kupersmith. *Id.* at 104. Petitioner was examined for being "cranky" and "pulling his ear," but no fever or drainage was evident. *Id.* By September 28, 2000, however, Petitioner had developed a fever and an ear infection. *Id.* On September 30, 2000, a new antibiotic was prescribed. *Id.*

On October 6, 2000, another EEG was conducted with some "episodes of eye fluttering." *Id.* at 105. Nevertheless, the EEG was determined to be normal. *Id.* at 134. On October 12, 2000, Dr. Rubin examined Petitioner for a follow-up of his eye fluttering. *Id.* at 106. During that examination, Dr. Rubin "confirmed the presence of an infrequent, *intermittent upbeat nystagmus*[32] *which had apparently evaded detection at [Petitioner's] many prior examinations*." *Id.* (emphasis added). Dr. Rubin referred Petitioner to a neuro-ophthalmologist for further examination of Petitioner's "intermittent vertical nystagmus." *Id.* at 109-110.

On October 23, 2000, Petitioner was evaluated by the Therapy Services of Greater New York and diagnosed with "gross motor and fine motor deficits." 10/2/02 Gov't Ex. L at 234. The "quality

[32] "Upbeat nystagmus" is a "vertical nystagmus with the fast phase upward occurring in lesions of the vermis cerebelli." DORLAND'S at 1296. The "vermis cerebelli" is the "narrow median part of the cerebellum, between the two lateral hemispheres." *Id.* at 2033. The "cerebellum" is the part of the brain "that occupies the posterior cranial fossa behind the brain stem and is concerned in the coordination of movements." *Id.* at 336.

of [Petitioner's] movement was also constantly compromised due to poor grading of tone." *Id*. at 235.

On October 30, 2000, Petitioner had a flu, was "very cranky," and was examined for an ear infection. 10/2/02 Gov't Ex. B at 105. Amoxicillin was prescribed. *Id*.

On November 7, 2000, Petitioner was examined by Dr. Michael J. Slavin, M.D., Chief Neuro-Ophthalmology, Medical Retinal Diseases at the Department of Ophthalmology at the North Shore Long Island Jewish Health System in Great Neck, New York ("Dr. Slavin"). *Id*. at 109-10. Dr. Slavin noted that Petitioner's "milestones" were delayed, but did not observe any vertical nystagmus and described the examination as "normal." *Id.* at 109. Dr. Slavin, however, had a question about a "lucency seen in the interpedancular cistern" in Petitioner's MRI. *Id*. Dr. Slavin noted, however, that after consulting with Dr. Zito, he felt that the June 22, 2000 MRI "lucency" observed was a "flow artifact" and not a "lesion." *Id*. at 110.

On November 16, 2000, Petitioner exhibited crying, cranky behavior. *Id*. at 111. Although Petitioner completed the course of Amoxicillin, he still had "mucusy eyes." *Id*. On November 17, 2000, Petitioner had drainage from his ear. *Id*. On November 27, 2000, Petitioner exhibited no eye "fluttering," but was "walking with a wide gait." *Id.* at 112. Dr. Turow then scheduled an "ortho[pedic] eval[uation]," because of "developmental issues." *Id*. Prevnar™[33] and HIB vaccines were administered. *Id.*

On December 12, 14, 16, 20, 2000 and January 8, 2001, Petitioner continued to receive medical care for fever, nasal infection, coughing, sinusitis, rash, and yeast infections. *Id*. at 113-14.

On January 10, 2001, Petitioner was tested and evaluated by Ms. Amy Bogatch, M.S.-CCC, Speech/Language Pathologist at the Nassau County Early Intervention Program in Mineola, New York ("Ms. Bogatch"). *See* 10/2/02 Gov't Ex. K at 199-201. She observed that Petitioner "exhibits significant delays in both receptive and expressive language abilities . . . Further weaknesses were noted in the area of oral-motor skills and feeding as [Petitioner] is unable to chew and swallow solid foods or drink from a cup. Drooling is apparent." *Id*. at 201.

From January 11, 2001 to February 27, 2001, Petitioner was seen by Dr. Neil Sadick, M.D. and Dr. Robert Hayman, M.D. for scabies and eczema. *See* 10/2/02 Gov't Ex. B at 115-19, *see also* 10/2/02 Gov't Ex. N at 278-82.

On February 16, 2001, Petitioner was examined again by Dr. Turow for swollen glands ,and "developmental delay" was noted. *See* 10/2/02 Gov't Ex. B at 120.

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[33] "Prevnar™" is a "trademark for a preparation of pneumococcal heptavalent (or 7 valent) conjugate vaccine." DORLAND'S at 1505. This vaccine is used for immunization of children who are "high risk for pneumococcal infection, including those with . . . immunocompromising conditions. *Id*. at 1999.

On March 8, 2001, Petitioner underwent a "functional visual evaluation" at the Long Island Infant Developmental Program. *See* 10/2/02 Gov't Ex. L at 141-42. Despite numerous prior examinations by Dr. Rubin, an ophthalmologist, and Dr. Kupersmith, a neuro-ophthalmologist, Petitioner was now diagnosed with "vestibular problems"[34] and "demonstrated a 25%+ delay in visual-motor skills." *Id*. at 242.

On May 14, 2001, Dr. Rubin evaluated Petitioner, because of observations of "nystagmus" and "esotropia" in the preceding few weeks. *See* 10/2/02 Gov't Ex. B at 124. Dr. Rubin noted that Petitioner "was slightly more hyperopic[35] than other children." *Id*.

On May 18, 2001, Petitioner received another Prevnar™ vaccination. *Id.* at 32, 127. Dr. Turow noted that Petitioner was still undergoing physical therapy, occupational therapy, and speech therapy and was working with a specialist for the visually - impaired to address "disorientation in movem[en]ts." *Id*. at 126. On May 19, 2001, Petitioner was examined in the emergency room for fever, "draining" ears and "goopy eyes," and was prescribed Amoxicillin. *Id*. at 128. On May 22, 2001, Dr. Turow noted that Petitioner continued to experience a fever with mouth sores, and his ear tubes were "draining profusely." *Id*. A different antibiotic, Ceftin™ was prescribed. *Id.*

On June 7, 2001, Petitioner experienced a rash that was treated as potential scabies. *Id.* at 130.

On June 20, 2001, Petitioner had a pediatric cardiology examination, of no consequence. *Id*. at 129.

On July 26, 2001, Petitioner was examined by Sheila McElhern, M.S. Ed., TVI, at the Nassau County Early Intervention Program, Nassau County Department of Health, who reported that Petitioner "has been diagnosed with intermittent vertical nystagmus and vestibular problems of undetermined cause." 10/2/02 Gov't Ex. L at 243. His MRI and other neurological tests were inconclusive. *Id.* He "demonstrates frequent squinting and head tilts, poor balance, and trips and falls frequently." *Id.*

On July 3, 2001, Dr. Steven B. Ritz, M.D., Associate, Pediatric Cardiology at the Children's Heart Center at North Shore Hospital, reported no cardiology concerns, but noted that Petitioner had a "paradoxial reaction following his 2-month pertussis vaccination." 10/2/02 Gov't Ex. B at 131. In addition, Petitioner had a "history of developmental delay and intermittent horizontal nystagmus." *Id*.

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[34] "Vestibular nystagmus" is "nystagmus due to disturbance of the vestibular system; eye movements are rhythmic with a slow and fast component." DORLAND'S at 1296.

[35] Hyperopia is "[l]ongsightedness; that optic condition in which only convergent rays can be brought to focus on the retina." STEDMAN'S at 923.

On July 11, 2001, Petitioner was examined for "not walking right - foot turns in and he seems to be favoring his right foot." *Id*. at 137. In addition, Petitioner's left foot was "considerably warmer" than his right foot, but no swelling was detected. *Id*. His "gait" was "absolutely normal." *Id*. On July 23, 2001, another possible ear infection was noted. *Id*.

On August 14, 2001, Dr. Lydia Eviatar, M.D., Professor of Pediatric Neurology at the Long Island Campus of the Albert Einstein College of Medicine ("Dr. Eviatar"), conducted a "neurological consultation" to evaluate issues regarding Petitioner's "poor balance and episodes of upward gaze nystagmus with eye fluttering[.]" *Id.* at 134. Petitioner's past medical history indicates he was "doing well until 6 months of age, until he received a Pertussin shot." *Id*. The emergency work-up, however, was unremarkable, other than a CT scan showing a "slightly enlarged subarachnoid space." *Id*. Dr. Eviatar's evaluation concluded that:

> Neurological examination reveals [Petitioner] has a fleeting gaze, but is interactive, playful and nonverbal. Cranial nerve examination is normal and the parents had to elicit an episode of eye flutter, which was very brief by waking him up as he was falling asleep and shaking him around. There was no nystagmus or opsoclonus elicited during the examination. Motor tone is decreased and there is hyperlaxity of the ligaments. He is reaching for objects with no overt dysmetria, but has difficulty stacking blocks. A mild tremor is noted while doing so. He appears to be primarily left-handed. As mentioned, there is a broad-based ataxic gait and poor gross motor coordination. Self-stimulatory behaviors, such as jumping or running back and forth when excited are noted, as well as preservation of objects that can be spun or by Barbie dolls, which he can wave back and forth to see their hair move.
>
> My diagnostic impression is that the youngster has generalized gross motor and fine motor delays, as well as speech and language delay and some very mild pervasive developmental disorder features. The onset of eye movements immediately after the Pertussin shot is puzzling. We do see episodes of flutter or opsoclonus and developmental delay as a result of autoimmune encephalitis known as encephalopathy.

*Id*. at 135-36.

On September 20, 2001, Ms. Bogatch reported a REEI-2 reveals Petitioner's "receptive language at 14-16 month level . . . His expressive language appears to be at a 18-20 month level." 10/2/02 Gov't Ex. L at 245. Ms. Bogatch reported that she had spoken to Petitioner's occupational therapist and recommended that the services of a special education teacher be obtained. *Id*. at 245-46. Petitioner's "attention skills and his ability to focus to task are limited, his conceptual development is below age expectance, and his play skills are immature." *Id*. at 245.

On October 5, 2001, Ms. Joanne C. Villani, Physical Therapist with the Therapy Service of Greater New York, reported Petitioner's gross motor skills were at the twenty-one month level, although he was twenty-eight months old. *Id.* at 247.

On October 22, 2001, Petitioner had a two year examination with Dr. Rubin. *See* 10/2/02 Gov't Ex. B at 138. No nystagmus nor strabismus was evident. *Id*. Dr. Rubin concluded: "At this point I can provide no help in my search of any underlying diagnosis for [Petitioner.]" *Id*.

On November 5, 2001, Petitioner was examined by Dr. Turow for a sore throat, with cough and fever. *Id*. at 139.

In November 8, 2001, a comprehensive evaluation by the Early Childhood Development Program at Schneider Children's Hospital, North Shore - Long Island Jewish Health System was conducted. *See* 10/2/02 Gov't Ex. L at 249 "[C]oncerns include sensory-vestibular issues, speech and language, gross and fine motor development. All developmental milestones were reported delayed." *Id.* Petitioner's development was at a twenty-three month old level. *Id.* at 237. Petitioner's cognitive skills were tested on the Bagley Scale of Infant Development and reported as "within the Significantly Delayed range of functioning[.]" *Id*. at 237. Petitioner's physical development examination reported gross motor skills per the *Developmental Profile for Young Children* were:

> within the 20 month level, representing a 33% delay in balance and coordination skills. [Petitioner] demonstrates significant attentional difficulties which impede functional performance . . . He appears to have difficulty integrating and tolerating vestibular stimulation. He appears to under-react to tactile stimulation and displays difficulty with body awareness. He demonstrates delays in self-help skills in the area of feeding with regard to adequate use of a utensil, cup drinking and tolerating hard textures of food.

*Id*. at 238. Petitioner's "Language and Communication Development" examination reported:

> [Petitioner] inconsistently established appropriate eye contact with the evaluators. At times it appears that [Petitioner] lost eye contact and would stare beyond the person seated in front of him. This occurs throughout the evaluation, as [Petitioner] would appear related and focused one minute and then he would suddenly appear distant and disconnected from the environment and his surroundings. Receptive language skills were judged to be at the 1 year, 8 month level, indicating a 33% delay. Expressive language skills were judge to be at the 1 year, 11 month level, indicating a 23% delay. Informally, overall intelligibility was judged to be good at the single word level for both known and unknown contexts. At the phrase level,

> overall intelligibility was judged to be fair-poor for known contexts and poor for unknown contexts. Intelligibility was compromised by [Petitioner's] use of jargon. Oral motor weaknesses and feeding concerns were noted as well.

*Id*. at 239.

> The "Adaptive Behavior" examination reported:
>
> [Petitioner] obtained a standard score of 66, 1st %ile on the *Vineland* which places his self-help skills within the Low range of functioning and more than two standard deviations below the norm. He is not toilet trained, nor does he indicate a soiled diaper. He will eat and tolerate a variety of foods, and self feeds with a spoon and fork, although with some spillage. . . Reportedly, [Petitioner] displays difficulty lateralizing his tongue, and often uses his fingers to push foods back into his mouth, as they often spill out. He is unable to competently drink from an open cup (without much spillage) but can drink from a sippy cup, suck from a straw and continues to drink two bottles per day. Assistance is needed with dressing and undressing, although [Petitioner] will extend his arms appropriately and can remove his hat, coat, and gloves independently. He requires assistance with tooth brushing, face washing, and does not yet actively participate in bathing.

*Id*.

On November 8, 2001, Cheryl Seltzer, OTR, reported that Petitioner's status demonstrated "mildly low muscle tone in his trunk and face. Frequent drooling is observed . . . He demonstrates asymmetry with regard to arm and hand function as well as increase tone in his right upper extremity . . . Overall movement patterns appear to display limited trunk rotation and lack of integrated movement patterns. Movement quality is immature when negotiating his environment." *Id*. at 256. Under sensory motor processing, Petitioner was described as having "difficulty integrating and tolerating vestibular stimulation . . . appear[ing] to under-react to tactile stimulation." *Id.* at 258. Petitioner's gross motor and fine motor-perceptual skills both evidenced a 33% delay. *Id.* Petitioner's "gross motor skills . . . represent [] a 33% delay in balance and coordination. *Id*. at 257. Petitioner's "fine motor - perceptual skills . . . represent [] a 33% delay. He demonstrates difficulty with bilateral integration skills, coordinated use of both sides of his body as well as decreased hand strength required for use of refined hand skills. He demonstrates difficulty with visual-perceptual skills. He demonstrates significant attentional difficulties which impede functional performance." *Id*. at 258. He "demonstrates some difficulty due to motor planning and difficulty tolerating movement experiences." *Id*. at 259.

On November 13, 2001, Petitioner was examined by Dr. Turow for a "wet" cough and possible strep infection. *See* 7/11/06 Pet. Ex. A at 62.

On December 4, 2001, Petitioner was examined by Dr. Turow for not eating and fever. *See* 10/2/02 Gov't Ex. B at 140. A virus was suspected. *Id*. On February 5, 2002, Petitioner was examined for fever and vomiting. *See* 7/11/06 Pet. Ex. A at 63. A virus was suspected. *Id*.

On February 23, 2002, Petitioner again was evaluated by Dr. Rubin for an "increased frequency of episodes of vertical nystagmus with a chin-up head position" that Petitioner's mother documented with a home video. *See* 10/2/02 Gov't Ex. B at 142. Dr. Rubin concluded that examination was, "essentially normal," but another neuro-ophthalmologist examination was recommended. *Id.*

On February 28, 2002, Dr. Kupersmith conducted a "neuro-ophthalmic follow[-]up," and concluded that Petitioner had a history of "some encephalopathy of some sort." 10/2/02 Gov't Ex. D at 175. Dr. Kupersmith did not see any remarkable change from his June 2000 evaluation, but confirmed nystagmus on Petitioner's right eye and that his left gaze was "conjugate jerk nystagmus." *Id*.[36] Dr. Kupersmith suggested that Petitioner's condition "may be some type of neuronal discharge phenomenon" and recommended that Petitioner try an anticonvulsant or Baclofen[37] under pediatric neurologist supervision. *Id.*

Sometime in March 2002, Petitioner's mother died of a stroke. *See* Gov't Ex. K at 204; *see also* 7/11/06 Pet. Ex. A at 71.

On March 26, 2002, Petitioner had a low-grade fever, coughing, and runny nose and was diagnosed by Dr. Turow with a virus. *See* 7/11/06 Pl. Ex. A at 64. On March 27, 2002, Ms. Bogatch reported that Petitioner continued to exhibit "overall delays in language, articulation, and oral motor skills." *See* 10/2/02 Gov't Ex. K at 209. Petitioner experienced "delays of up to and greater than 33% in both receptive and expressive language skills." *Id*. at 209-210.

On April 11, 2002, Petitioner was examined for swelling of the right eye and was diagnosed with and treated for conjunctivitis. *See* 7/11/06 Pl. Ex. A at 63. On April 12, 2002, Petitioner's left eye was swollen with a discharge. *Id*. at 64. Conjunctivitis was diagnosed by Dr. Turow. *Id*. On April 18, 2002, Petitioner had a temperature and experienced another seizure. *Id*. at 65.

On April 17, 2002, following an "event that was consistent with seizure," Dr. Pavlakis examined Petitioner and noted that he experienced "alteration of consciousness over a long period of time, lasting 20 minutes to hour," and showed "some change in color." 10/10/02 Pet. Ex. at 2.

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[36] "Jerk nystagmus" is defined as "nystagmus which consists of slow movement in one direction, followed by a rapid return movement in the opposite direction[.]" DORLAND'S at 1296.

[37] "Baclofen" is an "analogue of y-aminobutyric acid administered . . . as a muscle relaxant and antispastic in treatment of spasticity of spinal origin . . . it is used also . . . to treat spacity of cerebral origin[.]" DORLAND'S at 191.

Dr. Pavlakis concluded that this episode was similar to the July 20, 1999 episode and recommended another EEG. *Id.*

On April 30, 2002, Petitioner filed a Petition, pursuant to the Vaccine Act, 42 U.S.C. § 300aa-1, in the United States Court of Federal Claims.

* * *

On May 1, 2002, at a pre-op for an EEG, MRI, and MRA, Dr. Turow noted he had been on Klonopin™[38] until five days ago, that was stopped because of nystagmus and sleepiness. *See* 7/11/06 Pet. Ex. A at 66.

On May 3, 2002, in order "[t]o rule out aneurysm," Petitioner had a magnetic resonance angiography ("MRA"). 7/24/06 Pet. Ex. A at 1. The MRA was determined to be unremarkable, because it revealed "[n]o intracranial vascular anomalies." *Id.*

On May 10, 2002, Plaintiff had a temperature of 102°F, was vomiting mucus, and was breathing heavily. *See* 7/11/06 Pl. Ex. A at 66. A virus was suspected since a strep test was negative. *Id*. at 66-67. On July 9, 2002, Dr. Turow noted that Petitioner was experiencing fatigue, no appetite, cough, and irritability. *Id*. at 69. A virus was suspected. *Id*. On July 15, 2002, a urine test for metabolic screening was negative. *Id*.

On July 24, 2002, Ms. Bogatch reexamined Petitioner. *See* 10/2/02 Gov't Ex. at 203-04. She reported that Petitioner's expressive language appears to be at twenty-two to twenty-four month level with scattering of skills up to twenty-eight months. *Id*. at 203. Significantly, she reported that Petitioner:

> exhibits numerous articulation errors, which consist of substitutions of one sound for another, omissions of sounds in the initial, medial, and final positions of words, and simplifications of blends. Intelligibility is judged to [be] severely delayed.
>
> [Petitioner's] mother passed away approximately 3 months ago. [Petitioner's] speech and language skills have been affected by this tragedy. He also experienced a seizure

[38] "Klonopin™" is a trademark for a "preparation of clonazepam." DORLAND'S at 982. "Clonazepam" is a "benzodiazepine used as an anticonvulsant in the treatment of atonic and myoclonic seizures[.]" *Id*. at 377.

> approximately 8 weeks ago. After the seizure, his speech became extremely unintelligible and it did not improve for approximately 3-4 weeks. His speech and language skills have been improving over the last 6 weeks.

*Id*. at 203-04. CPSE services were approved. *Id*. at 204. In late September 2002, Petitioner began attending "Variety Preschoolers Workshop," a Preschool Special Education Service set up by the Public School District of Manhasset, New York. *Id*.

On August 9, 2002, during Petitioner's three year examination, Dr. Turow reported that Petitioner's nystagmus had improved, but was evidenced when Petitioner was tired. *See* 7/11/06 Pl. Ex. A at 71. No suspicious seizure activity was reported. *Id*. Dr. Turow, however, noted "developmental delay," as Petitioner was not toilet trained, had gross motor weakness, and some speech difficulty. *Id*. On August 11, 2003, at Petitioner's four year examination, Dr. Turow noted Petitioner was "making progress." *Id.* at 79.

On August 12, 2004, Petitioner had a five year examination with Dr. Turow before starting kindergarten in an "inclusion prog[ram]" at "Shelter Rock," where he would continue to receive occupational, physical, and speech therapy. *Id.* at 85. A "DT pediatric" vaccine and an IPV were administered, without incident. *Id.* at 86.

On October 26, 2004, Dr. Eviatar noted on a prescription pad that Petitioner's "intermittent vertical nystagmus" was "most likely secondary to post DPT encephalopathy." *See* 10/31/05 Pet. Ex. 1.[39]

On April 27, 2005, in response to symptoms of vertigo, a radiologist reviewed the May 3, 2002 MRI, saw "no evidence of temporal lobal pathology," and found "evidence of bilateral tonsillar herniation of the cerebellar tonsils[40] of approximately 7-8mm." 7/24/06 Pet. Ex. B at 1-2.

On April 28, 2005, Dr. Neil A. Feldstein, a neurosurgeon at the Presbyterian Medical Center in New York City ("Dr. Feldstein"), examined Petitioner and observed that he exhibited "a mild upbeat nystagmus," as well as an extension of his head at the neck. *See* 10/24/05 Gov't Ex. at 13. Dr. Feldstein reviewed previous MRIs. *Id*. at 13-14. According to Dr. Feldstein, the first MRI in 2000 "shows fullness to the posterior fossa without tonsillar herniation." *Id.* at 13. The second MRI,

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[39] At the remand hearing, Dr. Eviatar's opinion regarding the link between the vaccine and Petitioner's injury was presented in a November 21, 2008 letter written in response to joint questions submitted by both counsel. In the letter, Dr. Eviatar stated: "This is to confirm that on 10/26/04 I wrote a handwritten Rx referring [Petitioner] for a consultation . . . I wrote: "most likely secondary to DPT encephalopathy" quoting Dr. T[urow's] comments when he referred [Petitioner] for consultation." 12/19/08 Gov't Ex. I.

[40] "Tonsil of the cerebellum" is a "rounded lobule on the underside of each cerebellar hemisphere, continuous medially with the uvula of the cerebellar verones." STEDMAN'S at 1999.

a scan from 2002, however, "is consistent with Chiari malformation," including "a 6-7 mm tonsillar herniation and significant deformation and compression of the inferior portion of the cerebellum at the level of foramen magnum." *Id.* Dr. Feldstein suggested that Chiari malformation was the sole explanation that tied Petitioner's symptoms together. *Id.* at 14. Dr. Feldstein requested a MRI of the entire spinal cord, "to reassess the anatomy in the posterior fossa." *Id.* He believed that Petitioner's condition would improve with a "suboccipital decompression."[41] *Id.*

On May 10, 2005, Petitioner had another MRI of his brain, cervical/thoracic/lumbar spine, and a cerebrospinal fluid flow study. *See* 12/29/05 Pet. Ex. at 3. The MRI results were "consistent with Chiari I Malformation[42] with 9mm of inferior cerebellar tonsillar ectopia." *Id.* The fluid study showed "less flow" possibly "below the foramen magnum compared to above the foramen magnum." *Id.*

On May 16, 2005, Dr. Feldstein performed an "elective suboccipital decompression" on Petitioner at Columbia Presbyterian Medical Center. 9/15/05 Pet. Ex. at 368. Dr. Feldstein used "B[rain stem] A[uditory] E[voked] R[esponse] and S[omato] S[ensory] E[voked] P[otential] monitoring." *Id.* at 392. The monitorings and "pulsation of the cerebellum and upper cervical canal" improved during the suboccipital bony decompression. *Id.* at 393. After the surgery, Petitioner was taken to the pediatric intensive care unit "for post-op management." *Id*. at 368. Petitioner remained stable during his hospital stay and was released on May 18, 2005. *Id*. at 368.

On June 7, 2005, Dr. Feldstein conducted a "first post-op check." 12/29/05 Pet. Ex. at 4. Petitioner did not report any specific post surgery complications, and Dr. Feldstein noted that Petitioner was "healing nicely," despite "minor pain and irritability." *Id.*

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[41] "Suboccipital" refers to "[b]elow the occiput or the occipital bone. 2. Denoting certain muscles, nerves, a nervous plexus, or triangle of the neck below the occipital bone." STEDMAN'S at1856.

[42] "Chiari I Malformation" is "a *congenital* anomaly in which the cerebellum and medulla oblongata, which is elongated and flattened, protrude down into the spinal canal through the foramen magnum." DORLAND'S at 438 (emphasis added).

In a letter dated November 21, 2005, Dr. Pavlakis stated that at "no time during the period that I was following [Petitioner], did I think [Petitioner] had a clinically relevant Chiari malformation." 12/29/05 Pet. Ex. at 8. On that same date, Dr. Spitz addressed a letter to Petitioner's attorney concluding "[t]he attempt to blame a non-existent Arnold-Chiari Syndrome for the neurological and developmental abnormalities, after the vaccination, is moot." *Id*. at 10.

In a letter dated November 30, 2005 and addressed to Petitioner's attorney, Dr. Zito offered a reading of Petitioners' June 2000 and May 2002 MRIs. Dr. Zito found "that neither [MRI] shows any abnormality in the brain stem or spinal cord . . . [and] no evidence of Chiari I malformation". 12/29/05 Pet. Ex. at 3. "[T]he MRIs show no condition of the brain, brain stem or spinal cord, which would explain encephalopathy." *Id.*

On September 13, 2005, Dr. Turow noted that Petitioner's six year examination showed much improved balance and fine motor skills. *See* 7/11/06 Pet Ex. at 93. Although Petitioner was attending the first grade, he continued to receive special education services, but was improving in "cognitive issues." *Id.*

## II. PROCEDURAL HISTORY.

### A. The Initial Special Master Proceeding.

On April 30, 2002, Petitioner filed a petition with the Office of Special Masters seeking compensation for Petitioner's injuries. Petitioner alleged alternative theories of compensation under both the Vaccine Injury Table and a cause-in-fact theory. The case was initially assigned to Special Master E. LaVon French ("Special Master I"). Subsequently Special Master I retired, and on December 22, 2004, the case was reassigned to Special Master John F. Edwards ("Special Master II").

From October 2002 through April 2004, Petitioner periodically filed medical records.

During October 27-28, 2005, Special Master II took testimony from three fact witnesses: Petitioner's father; grandmother; and neighbor. In addition, Special Master II took testimony from the Petitioner's expert, Dr. Eugene Spitz, and the Government's expert, Dr. Max Wiznitzer. Dr. Spitz, however, only testified about Petitioner's Table claim and did not testify about Petitioner's causation-in-fact theory. During testimony, Dr. Spitz spoke about the meaning of a MRI that had not been filed. Therefore, Special Master II left the record open for more expert testimony on Petitioner's causation-in-fact theory.

On July 20, 2007, Special Master II convened a second hearing. In the interim, however, Dr. Spitz passed away. Petitioner retained a new expert, Dr. John Shane. At the hearing, Special Master II only allowed Dr. Shane to testify on issues regarding Petitioner's MRI, and Dr. Shane was prevented from offering any testimony about a new theory of causation.

On May 22, 2008, Special Master II issued an Unpublished Decision (Fact Witness/Medical Expert Credibility Ruling). Special Master II found in favor of the Government, dismissing both Petitioner's Table and causation-in-fact claims.

### B. The Initial United States Court Of Federal Claims Proceeding.

On July 7, 2008, Petitioner filed a Motion For Review in the United States Court of Federal Claims. On August 6, 2008, the Government filed a Response.

On October 21, 2008, the court issued a Memorandum Opinion and Final Order holding that Special Master II correctly determined that Petitioner did not establish a Table injury. *See John Doe 21*, 84 Fed. Cl at 46. The court also held that Special Master II failed to adhere to the burden of

proof established by the United States Court of Appeals for the Federal Circuit in *Althen* v. *Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), and instead required Petitioner to rebut the Government's alternative theory of causation before determining whether Petitioner's current condition causally was connected to a post-vaccine adverse reaction. *Id.* at 47-48. Special Master II erred in making a credibility determination about the medical records of Dr. Eviatar without testimony. *Id.* at 48. Finally, the court determined that Special Master II erred in prohibiting Petitioner's expert, Dr. Shane, from completing his testimony and fully presenting his theory about Petitioner's vaccines and their relationship to Petitioner's injury. *Id.* at 48-49.

Accordingly, the court remanded the case to Special Master Christian Moran ("Special Master III"), who was assigned the case following Special Master II's retirement, with "instructions to reopen the record to allow: Petitioner's Expert Dr. Shane to complete his . . . testimony; Dr. Eviatar to address [Special Master II]'s suspicions . . . ; and any additional rebuttal the Government requires." *Id.* at 50 (internal quotations omitted).

### C. The Remand Proceeding Before Special Master III.

On October 30, 2008, Petitioner filed the Supplemental Expert Report of Dr. Shane. On November 21, 2008, Petitioner also filed an Expert Report from Dr. Mary Norfleet Megson, a newly retained expert. The Government did not object to this additional testimony, although it exceeded the parameters set by the court regarding the remand. On the same date, the Government filed the Supplemental Expert Report of Dr. Wiznitzer.

On December 2, 2008, Special Master III convened a remand hearing. Petitioner called four witnesses: Petitioner's father; Dr. Shane; Dr. Megson; and Dr. Victor Turow, Petitioner's primary treating pediatrician. The Government called only Dr. Wiznitzer.

On December 19, 2008, the Government filed Exhibit I-V ("12/19/08 Gov't Ex. I-V"), which included Dr. Eviatar's written response to questions agreed on by both parties' counsel, Dr. Wiznitzer Supplemental Expert Report, and medical articles in support of that report.

On January 16, 2009, Special Master III issued a Decision On Remand Denying Entitlement, premised on two principal findings. *See Remand Decision* at *9. First, Special Master III found that Petitioner "was developing at a normal pace" between July 20, 1999, the date of his initial DTaP vaccination, and six months later, *i.e.*, March 2000. *Id.* In making this finding, Special Master III reviewed the medical records of Petitioner's two month, four month, six month, and nine month health maintenance visits, where Petitioner's "developmental progress was specifically reflected in [the] examinations." *Id.* In addition, Special Master III found that testimony by Petitioner's experts, Dr. Shane and Dr. Megson, did not contradict the conclusion that Petitioner was not "developmentally delayed at nine-months." *Id.*

Second, Special Master III found that the testimony of Dr. Spitz "was generally not relevant to determining whether [Petitioner] suffered a developmental delay," but primarily related to whether

Petitioner had suffered a Table injury, which was not an issue on remand. *Id.* at *21. Special Master III also found the testimony of Petitioner's other two experts, Dr. Megson and Dr. Shane, was not persuasive "[o]n critical points[.]" *Id.* Special Master III found that Dr. Megson was unable to "explain her opinion in such a way to demonstrate that her opinion [was] reliable." *Id.* at *22. Dr. Shane's opinions "were overstated" and "not well supported." *Id.* at *23.

Special Master III then proceeded to analyze Petitioner's two causation theories, using the previously discussed general findings to inform his decision. *Id.* at *24. As to Petitioner's first theory, *i.e.*, that the July 20, 1999 DTaP vaccination caused an encephalopathy resulting in Petitioner's injuries, Special Master III concluded that Petitioner failed to satisfy the logical sequence prong and the timing prong of the causation-in-fact test established in *Althen*, 418 F.3d at 1278 (holding that a Petitioner must show "a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and [] a showing of a proximate temporal relationship between vaccination and injury"). *See Remand Decision* at *24-35. As for the second theory, *i.e.*, that Petitioner's "current condition constitutes a sequella to the adverse reaction [that Petitioner] experience on July 20, 1999," Special Master III found that it was "not necessary to determine whether the DTaP vaccine caused an adverse reaction using the *Althen* three-part test, because the Government conceded that the vaccination caused an adverse reaction." *Id.* at *35. Instead, the relevant issue was whether Petitioner could establish that the residual effects or complications of the adverse reaction lasted more than six months. *Id.* Special Master III found that Petitioner was unable to show by a preponderance of the evidence that Petitioner's adverse reaction lasted longer than six months. *Id.* at *36.

### D. Current Proceeding Before The United States Court Of Federal Claims.

On February 17, 2009, the Petitioner filed a Motion For Review requesting that the court vacate the January 16, 2009 *John Doe 21 Remand Decision*, enter judgment on liability in favor of Petitioner, and proceed to the damages phase. *See* Pet. Mot. at 20.

## III. DISCUSSION.

### A. Jurisdiction And Standard Of Review.

Section 300aa-12(e) of the Vaccine Act authorizes the United States Court of Federal Claims to review the decision of a special master. *See* 42 U.S.C. § 300aa-12(e)(2) ("The United States Court of Federal Claims . . . have jurisdiction[.]"). The same section also authorizes the court, in reviewing a decision of a special master, to (1) uphold findings of fact and conclusion of law, (2) set aside any findings of fact or conclusion of law "found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or (3) "remand the petition to the special master for further action in accordance with the court's direction." *Id.*

Findings of fact by a special master are to be reviewed under an "arbitrary and capricious standard;" legal conclusions are reviewed under a "not in accordance with law standard;" and

discretionary rulings are reviewed for "abuse of discretion." *Saunders* v. *Sec'y of HHS,* 25 F.3d 1031, 1033 (Fed. Cir. 1994) (internal quotations omitted). The United States Court of Appeals for the Federal Circuit has held that "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines* v. *Sec'y of HHS*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). It is not the role of a court "to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence." *Lampe* v. *Sec'y of HHS*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal quotations omitted).

**B. Causation In Vaccine Act Cases.**

The Vaccine Act provides a petitioner with two ways to establish causation. *See De Bazan* v. *Sec'y of HHS,* 539 F.3d 1347, 1351-52 (Fed. Cir. 2008). First, the Vaccine Injury Table ("Table") provides a list of symptoms and injuries associated with each listed vaccine and a time frame for each symptom or injury to occur after the vaccine's administration. *See* 42 C.F.R. § 100.3. Causation is presumed if the petitioner can demonstrate by a preponderance of the evidence that the alleged injury satisfies the symptoms and time frame criteria listed in the Table. *See Capizzano* v. *Sec'y of HHS*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). The court previously affirmed the determination of Special Master II that Petitioner did not establish a Table injury. *See John Doe 21*, 84 Fed. Cl. at 46.

In the alternative, if a petitioner has suffered injury that does not meet the criteria set forth in the Table, the petitioner must establish causation-in-fact. *See De Bazan,* 539 F.3d at 1351 ("If, as here, the petitioner has suffered an injury that is not listed on the Table, or if the petitioner suffered an injury listed on the Table but not within the specified timeframe, [petitioner] is not afforded a presumption of causation and thus must prove causation-in-fact."). Causation-in-fact under the Vaccine Act is the same as a tort. *Id*. Therefore, a vaccine may serve as a cause-in-fact if it is a "*substantial factor in bringing about the harm*." *Id.* (emphasis added). To establish that the vaccine was a *substantial* factor, the petitioner must be able to show that the vaccine was more than a merely non-negligible contributor to the harm. *Id.* Petitioner, however, need not show that the vaccine was "the sole or even the predominant cause of [the] injury, just that it was a substantial factor." *Id.* Applying these principles, the United States Court of Appeals for the Federal Circuit has held that to prove causation-in-fact, the petitioner must establish by a preponderance of the evidence the three following criteria: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Once a petitioner has established a prima facie case, the burden of proof then shifts to the Government to: "establish[] alternative causation by a preponderance of the evidence[.]" *Walther* v. *Sec'y of HHS*, 485 F.3d 1146, 1151 (Fed. Cir. 2007). If the Government cannot establish alternative causation, the petitioner is entitled to recover damages. *Id.* Since the Government did not pursue an alternative theory of causation in this case, the only issue before the court is whether

the record establishes causation-in-fact by a preponderance of the evidence. *See De Bazan,* 539 F.3d at 1352 ("So long as the petitioner has satisfied all three prongs of the *Althen* test, she bears no burden to rule out possible alternative causes.").

### C. Petitioner's February 17, 2009 Motion For Review.

#### 1. Petitioner's Argument.

Petitioner lodges four objections to the January 16, 2009 Remand Decision. *See* Pet. Mot at 4-20. First, Special Master III's determination that Petitioner was developing normally between July 1999 and March 2000 is contrary to the evidence and is arbitrary and capricious. *Id.* at 4. Special Master III ignored "parental and medical testimony," instead relying on "unreliable and incomplete" medical records to reach a "less likely explanation" of the Petitioner's symptoms. *Id.* at 10.

Second, Special Master III erred in rejecting the expert testimony of Dr. Megson, a developmental pediatrician, who testified that Petitioner had "multiple symptoms consistent with calcium channel interference with inter-cell signaling and encephalopathy[,]" and these symptoms could be explained by the presence of a "pertussis toxin blockage of calcium channels[.]" *Id.* at 11, 13. In addition, Special Master III ignored peer-reviewed literature supporting Dr. Megson's opinion that a pertussis toxin block of calcium channels can "cause[] infections including chronic ear infections, vomiting, diarrhea and fever[.]" *Id.* at 13. Special Master III's error was compounded by the fact that he admitted that he "did not understand the supporting articles[.]" *Id.* at 11-12.

Third, Special Master III, failed to follow the court's prior credibility determination "that medical records of specials needs children are frequently incomplete." *Id.* at 14. Instead, Special Master III "arbitrarily and capriciously relied solely on the conclusions in those [medical] records and ignored all more credible [witness reports] of [Petitioner's] failure to meet developmental goals until he was diagnosed as delayed in early 2000." *Id.*

Fourth, Special Master III also misapplied the burdens of poof applicable in vaccine cases. *Id*. at 15. For example, Special Master III failed to follow *Althen's* guidance "that doubts about causation are to be resolved in favor of claimants." *Id.* at 16. In addition, Special Master III ignored Petitioner's experts, Dr. Spitz and Dr. Megson, concluding that Petitioner had not satisfied the requirement of showing a logical sequence of cause and effect. *Id.* at 17. Special Master III also chose to disregard expert and lay witness testimony that showed Petitioner "displayed numerous immediate and continuing symptoms of pertussis toxin poisoning and encephalopathy as early as July 21, 1999," the day after the DTaP vaccination. *Id.* at 19. More importantly, Special Master III misapplied the law by requiring that all "the symptoms of encephalopathy, including developmental delay, and not just onset symptoms, appear within a certain time frame." *Id.*

**2. The Government's Response.**

The Government responds that there is ample evidence in the record to support Special Master III's finding that Petitioner continued to develop normally for at least six months after receiving the DTaP vaccination on July 20, 1999. *See* Gov't Resp. at 9. Petitioner's claim that Special Master III inappropriately ignored witness testimony is "nothing more" than an attempt to relitigate the case. *Id.* at 10. Special Master III conducted a thorough review of the medical records and was reasonable in concluding that Petitioner's four month, September 14, 1999 health maintenance report was normal. *Id.* at 11.

In addition, Petitioner's argument that the law of the case precluded Special Master III from discrediting the fact witness' testimony is incorrect. *Id.* at 12. The court's October 21, 2008 Memorandum Opinion and Final Order regarding the DTaP vaccination vacated Special Master II's determination only to the extent he failed to obtain testimony from Dr. Eviatar and allowed Dr. Shane to complete his testimony. *Id.* The opinion did not vacate the other credibility determinations made by Special Master II about the fact witnesses. Accordingly, Special Master III was bound by the those previous determinations. *Id.*

Despite Petitioner's claims, Special Master III articulated sound reasons for rejecting the expert testimony of Dr. Megson, including the fact that she had "relatively little experience with caring for children less than one-year old[.]" *Id.* at 17. Special Master III properly concluded that her theory was unreliable, since Dr. Megson "was unable to explain her opinion or the medical articles attached to her report in a clear manner." *Id.* at 18. Moreover, there is nothing in the record to substantiate the assertion that Special Master III did not understand the proffered medical literature. Therefore, Petitioner failed to demonstrate a "proximate temporal relationship between the vaccination and the injury." *Id.* at 19.

**3. The Court's Resolution.**

The United States Court of Appeals repeatedly has upheld the application of the *Althen* three-part test, requiring a petitioner seeking to establish causation-in-fact for a non-Table injury to show: "'(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.'" *See Andreu* v. *Sec'y of HHS*, __ F.3d __ 2009 WL 1688231, at *5 (Fed. Cir. June 18, 2009) (quoting *Althen*, 418 F.3d at 1278). The court will address the first and third *Althen* elements and then analyze the second.

**a. Petitioner Established A Medically Plausible Biological Theory.**

The United States Court of Appeals for the Federal Circuit requires that a petitioner show by a preponderance of evidence: "a medical theory causally connecting the vaccination and the injury[.]" *Althen*, 418 F.3d at 1278. In determining whether a petitioner has established a medical theory the court has not required that a petitioner "prove their theory is more likely than not, but

rather that their medical theory is biologically plausible." *See Doe 11* v. *Sec'y of HHS*, 83 Fed. Cl. 157, 176 (2008) (internal quotations omitted).

In this case, Special Master III made no finding regarding whether Petitioner has shown a medical theory causally connecting the vaccination and the injury, because he determined that: "[Petitioner] has not met his burden with regard to prongs two and three. (No finding is made with regard to prong one.)" *See Remand Decision* at *25. Petitioner alleges that the DTaP vaccine caused Petitioner to suffer an encephalopathy. *See* Pet. Mot. at 19. A medical theory causally connecting DTaP and encephalopathy has been well recognized by the Office of Special Masters. *See Perez* v. *Sec'y of HHS,* 2008 WL 763301, at *40 (Fed. Cl. Spec. Mstr. March 4, 2009) (finding "as a matter of fact, that encephalopathy can be caused by the [p]ertussis component of the DTaP vaccine which [petitioner] received on 17 December 2003."); *see also Nordwall* v. *Sec'y of HHS,* 2008 WL 857661, at *11 (Fed. Cl. Spec. Mstr. Feb. 19, 2008) ("Dr. Shane opined that [the petitioner] suffered an encephalopathy caused by the DTaP vaccine and this encephalopathy caused his death."). In addition, the Table recognizes that a vaccine containing pertussis can cause encephalopathy. *See* 42 C.F.R. § 100.3 (linking "[v]accines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (*e.g.*, DTP, DTaP, P, DTP-Hib)" with "[e]ncephalopathy")).

**b. Petitioner Established A Proximate Temporal Relationship.**

The United States Court of Appeals for the Federal Circuit has held that: "the proximate temporal relationship prong [of *Althen*] requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *De Bazan,* 539 F.3d at 1352. Strong temporal evidence is most important "in cases involving contemporaneous events other than the vaccination, because the presence of multiple potential causative agents makes it difficult to attribute 'but-for' causation to the vaccination. After all, credible medical expertise may postulate that any of the other contemporaneous events may have been the sole cause of the injury." *Pafford* v. *Sec'y of HHS,* 451 F.3d 1352, 1358 (Fed. Cir. 2006). The onset of symptoms has been determined to be temporally proximate, if they begin less than twenty-hour hours after the administration of the vaccine. *See Loving* v. *Sec'y of HHS*, 86 Fed. Cl. 135, 147 (2009) (observing "[t]hat early experience taught that such adverse reactions to pertussis vaccine could occur within 72 hours after administration, establishing a maximum time for reaction but no minimum").

The Government concedes that Petitioner suffered a hypotonic-hyporesponsive event on July 20, 1999 following the initial DTaP vaccination. *See* Gov't Resp. at 5; *see also* 12/2/08 TR at 1006.

**c. Petitioner Established A Logical Sequence Of Cause And Effect.**

The United States Court of Appeals for the Federal Circuit has instructed special masters and the court that: "A logical sequence of cause and effect means what it sounds like - the claimant's theory of cause and effect must be logical. Congress requires that, to recover under the Vaccine Act,

a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury." *Capizzano*, 440 F.3d at 1326 (internal quotations omitted). A logical sequence of cause and effect can be supported by reputable medical or scientific explanation. *See Althen*, 418 F.3d at 1278. In particular, the testimony of treating physicians is "quite probative," since they "'are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Andreu*, 2009 WL 1688231, at *6 (quoting *Capizzano*, 440 F.3d at 1326).

Dr. Victor Turow, M.D., F.A.A.P. is a member of the Department of Pediatrics at North Shore University Hospital. Dr. Turow has been Petitioner's primary pediatrician since treating Petitioner on October 4, 1999 and remains so. *See e.g.*, 10/2/02 Gov't Ex. B at 54-55, 62-63, 67-68, 75-76, 82, 84, 103-05, 111-13, 120, 122, 126, 128, 130, 137, 140; 7/11/06 Pet. Ex. A at 32-34, 50, 66, 69, 71, 73-76, 79, 81-83, 85, 87-91, 93, 95; *see also* 12/2/08 TR at 1012.

At the December 2, 2008 remand hearing, Dr. Turow testified about the logical sequence between the July 20, 1999 vaccination and Petitioner's injury:

PETITIONER'S ATTORNEY: Just want to go back to your letter of June 19th, 2007. It says – you read out, '[Petitioner] may well have had a vaccine reaction with developmental ramifications.' In describing that you said it's possible, but not definite. Can you tell if it's more likely than not? Is it possible, or is that beyond the estimation at this point?

DR. TUROW: I think it's beyond estimation. I would be able to answer more honestly – it's very clear cut to me, just speaking personally – if I have a child who gets a vaccine and within six to twelve hours, let's say – or even within twenty-four hours – has a catastrophic result, then I have to believe that that leads to the vaccine.

And common sense – although common sense doesn't always tell the truth – but you know, if I had that I could say . . . when the dots are a little harder to connect it's much more difficult to say. But it's not impossible. We just don't always know. Particularly when – *if I could find another reason* I would say fine. But the truth is there are plenty of kids with

> developmental delay for whom we have no reason. So it's very difficult to say . . . [W]e all found it difficult to objectively connect the dots. But we didn't feel that it was therefore impossible that it was the cause. It's not – nothing is impossible. It's – you know, I can't say that. I can't say that it is or it isn't. I just don't have concrete evidence to connect the two.

*See* 12/2/08 TR at 1057-58, 1061 (emphasis added).

Special Master III found Dr. Turow's testimony "sincere and honest," but it fell short of the preponderance of evidence standard required to satisfy "a finding of a logical sequence of cause and effect," relying on two decisions by the United States Claims Court for the proposition that equivocal testimony cannot support a finding of causation. *See Remand Decision* at *28 (citing *Van Epps*. v. *Sec'y of HHS*, 26 Cl. Ct. 650, 654 (1992); *Doe* v. *Sec'y of HHS*, 19 Cl. Ct. 439, 450 (1990)). In doing so, Special Master III erred as a matter of law.

The United States Court of Appeals for the Federal Circuit, however, recently held that the testimony of a treating physician can establish a logical sequence of cause and effect, even where the treating physician cannot unequivocally state that the vaccination caused the injury. *See Andreu,* 2009 WL 1688231 at *6 (explaining that where the testimony of one of the petitioner's treating physicians "was not as unequivocal as the [testimony of another treating physician,] . . . read as a whole . . . [it may support] a causal connection between the DPT vaccine and [the petitioner's injury]").

In this case, Dr. Turow first began seeing Petitioner in October 1999. Petitioner is now ten years old, and Dr. Turow is still his primary pediatrician. Although Dr. Turow did not testify that the July 20, 1999 vaccine definitely caused Petitioner's condition, he "believed" that was the case here. *See* 12/2/08 TR at 1061.

Moreover, there was no other evidence that explained Petitioner's injury. When asked if Petitioner's records indicated any accident or other trauma that could cause Petitioner's developmental delay, Dr. Turow responded: "No. No." *Id.* at 1052. Dr. Turow also "found no cause - other than the [] vaccination - to explain" Petitioner's injury. *Id*.; *see also Andreu,* 2009 WL 1688231 at *12; *see also Liable* v. *Sec'y of HHS*, 2000 WL 1517672 at *4 (Fed. Cl. Sept. 7, 2000) (holding that a claimant was entitled to compensation where she experienced a seizure shortly after her DPT vaccination and doctors, despite extensive testing, "failed to identify any other cause for [her] chronic neurologic disorder.").

The *Andreu* court also emphasized that "[a] treating doctor's recommendation to withhold a particular vaccination can provide [further] probative evidence of a causal link between the

vaccination and an injury a claimant has sustained." *See Andreu,* 2009 WL 1688231 at *7; *see also Capizzano*, 440 F.3d at 1326 ("[T]he chief special master erred in not considering the opinions of the treating physicians who concluded that the vaccine was the cause of [the claimant's] injury" and who had recommended that she receive no future hepatitis B inoculations.). Likewise, in this case, Petitioner's medical records reflect that acellular pertussis was withheld, "because of prior hypertonic hyporeflexic episode." *See* 10/2/02 Gov't Ex. B at 52; *see also* 12/2/08 TR at 1042 (DR. TUROW: "[T]he decision was made after [Petitioner's] reaction to the very first vaccine that they would take out the P component of the DTaP and just give him the DT.").

For these reasons, the court has determined that Dr. Turow's testimony, viewed as a whole, and the inability to find any other cause of Petitioner's injury, combined with the decision to withhold acellular pertussis, establish, by a preponderance of evidence, a logical sequence of cause and effect showing that the vaccination was the reason for Petitioner's injury. *See Andreu,* 2009 WL 1688231 at *6-7; *see also Althen,* 418 F.3d at 1278.

Special Master III also erred in determining that "[Petitioner's] medical history after April 2000 [is] generally not relevant to determining [that] the July 20, 1999 DTaP vaccine caused [Petitioner's] developmental delay." *See Remand Decision* at *6. To the contrary, the complete medical history of a petitioner is relevant in ascertaining a logical sequence of cause and effect, because significant symptoms may develop that explain earlier events. *See Andreu*, 2009 WL 1688231 at *12 (stating that the special master must consider "the record evidence as a whole and the totality of the case.") (quoting *Knudson* v. *Sec'y of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994)). Selective review of a Petitioner's medical records in isolation and only within a limited time frame can result in an erroneous determination about cause and effect of a potential vaccine injury, particularly in children. In the court's judgment, that is what happened here. *See Althen*, 418 F.3d at 1281 ("[B]ecause the Special Master's decision was not in accordance with law, the trial court was permitted to review the evidence anew and come to its own conclusion. So long as the record contained sufficient evidence upon which to base predicate findings of fact and the ultimate conclusion of causation . . . the trial court was not required to remand.") (citations omitted).

Three months after Petitioner's first vaccination and one month after his second vaccination, on October 4, 1999, Dr. Turow recommended that Petitioner have an eye examination, because Petitioner's parents questioned whether Petitioner "may have had a lazy eye with respect to that deviated left eye that Dr. Barrone had noted. And there was a question mark about it. It is not always obvious. So that along with the possibility that he had a blocked tear duct was the reason I asked the family to go see the ophthalmologist." *See* 12/2/08 TR at 1014; *see also* 10/2/02 Gov't Ex. B at 57. On November 10, 1999, Steve E. Rubin, M.D., a pediatric ophthalmologist, conducted an examination but did not detect nystagmus. *See* 10/2/02 Gov't Ex. B at 57. The reliability of that examination, however, later was questioned by Dr. Rubin during a subsequent October 12, 2000 examination when he confirmed "the presence of an infrequent, intermittent upbeat nystagmus" and, to his credit, conceded that this symptom "apparently evaded detection at [Petitioner's] many prior examinations." *See* 10/2/02 Gov't Ex. A at 106. The significance of the upbeat nystagmus in children is that it is associated with brainstem and cerebellar disease. *See* Robert M. Kliegman,

M.D., Richard E. Behrman, M.D., Hal B. Jenson, M.D., Bonita F. Stanton, M.D., NELSON TEXTBOOK OF PEDIATRICS, 18th ed. (2007) ("NELSON'S") at 2436.

A month after Dr. Rubin confirmed the presence of nystagmus, Petitioner was walking with a "wide gait." *See* Gov't Ex. B at 112. In children, "[c]erebellar ataxia produces a broad-based unsteady gait, and if severe, the child requires support to prevent falling." NELSON'S at 2439; *see also id*. at 2488 (Acute cerebellar ataxia is a condition "thought to represent an autoimmune response to [a] viral agent affecting the cerebellum."). By July 26, 2001, Petitioner's medical records reflect "poor balance . . . [Petitioner] trips and falls frequently." 10/2/02 Gov't Ex. L at 243. But the onset of this condition is sudden and the effect on the trunk "can be so severe that the child is unable to stand or sit." NELSON'S at 2488. How would this condition manifest in a child who is not walking? The record evidences that on November 8, 1999, when Petitioner was six months old, four months after his first vaccination and two months after the second vaccination, Petitioner was unable to roll over or sit-up without support. *See* 10/2/02 Gov't Ex. B at 56. Petitioner, however, was able at least to roll to his side at two months prior to the vaccine and may have been able to sit by four months. *See* 10/2/02 Gov't Ex. A at 34, 51. This digression was a missed developmental milestone. *See* http://www.medem.com/medlib/article, American Academy of Pediatrics Developmental Milestones - Developmental Health Watch ("doesn't roll over in either direction (front to back or back to front) by 5 months."). Special Master III, however, erred in minimizing the effect of a delayed milestone in this case, because: "Delayed motor milestones and truncal ataxia are typical" with cerebellar injury. NELSON'S at 2488. It is undisputed that the initial vaccine resulted in a hypotonic-hyporesponsive event and some manifestation of encephalopathy. But encephalopathy and Chiari malformation, both "are prominently associated with ataxia because of their destruction or replacement of the cerebellum." *Id.* at 2488. Therefore, Petitioner's expert, Dr. Spitz, was correct in opining that Petitioner experienced encephalopathy. *See John Doe 21*, 84 Fed. Cl. at 33-35. And, the Government's expert, Dr. Wiznitzer, was correct in opining that Petitioner experienced encephalopathy and Chiari I malformation. *Id*. at 38-40. The presence of both of these neurological manifestations is consistent with overlying cerebellar ataxia. The likelihood that the initial vaccination triggered this cerebellar injury is further evidenced by the fact that by October 4, 1999 nystagmus may have been present, but escaped Dr. Rubin's attention or simply was misdiagnosed. *See* 10/2/02 Gov't Ex. A at 106.

Special Master III concluded that Petitioner showed "some signs of developmental delay in January 2000." *Remand Decision* at *1. The record, however, reflects that Petitioner showed developmental delay on November 9, 1999. *See* 10/2/02 Gov't Ex. B at 56. Special Master III also concluded that Petitioner failed "to establish that any adverse reaction to the July 20, 1999 DTaP vaccine lasted more than six months." *Remand Decision* at *1. The record, however, establishes that Petitioner's "adverse reaction" manifested on July 20, 1999, likely was manifest on October 4, 1999 during Petitioner's examination, and clearly was manifested by November 8, 1999 at his six month evaluation when Petitioner's regressed motor skills were first observed – all within four months of the first vaccination.

## IV. CONCLUSION.

For these reasons, the court has determined the record evidences that Petitioner's injury was caused by the vaccination. Accordingly, Petitioner's Motion for Review is granted. The January 16, 2009 Remand Decision by Special Master III is vacated. The case is remanded to Special Master III for an award of compensation to the Petitioner, reasonable attorney fees, and other costs.

**IT IS SO ORDERED**.

s/ Susan G. Braden
**SUSAN G. BRADEN**
**Judge**